Attorney Dkt. No. 001107.76459

Page 3

#### The Amendments

Claim 23 has been amended to correct a perceived lack of antecedent basis. Claim 24 has been amended to remove blood and saliva from the Markush group. It is respectfully submitted that neither of these amendments adds new matter or raises any new issues for consideration of patentability.

These amendments were not made sooner because the deficiency was not noted earlier in the case of claim 23. In the case of claim 24, blood was not deleted sooner because applicants understood that subject matter to be patentable. Claim 24 was not sooner amended to remove saliva, because the limited application of the rejection to only certain subject matter was not fully appreciated.

### The Rejection of Claims 24-28, and 37-38 Under 35 U.S.C. § 103 (a)

Claims 24-28, and 37-38 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Brugieres et al. (Cancer Research, Feb. 1993, vol. 53, pp 452-455) in view of Gonzalez-Zulueta (Cancer Research 1993), Merlo et al., (Cancer Research 1994), and Ah-See et al. (Cancer Research, 1994). Applicants respectfully traverse with regard to claims 24-28 and 37. Claim 38 has been canceled.

Each of claims 38-45 was dependent on claim 24, each reciting a different specimen mentioned in the Markush group of claim 24. Only claim 38 (reciting blood; now deleted) of the group of claims 38-45, was rejected over prior art. Applicant believes that removal of "blood" from the Markush group of claim 24 thus renders claim 24 allowable over the prior art, like each



Attorney Dkt. No. 001107.76459

Page 4

of its constituent Markush elements recited in dependent claims 39-45. If claim 24 is allowable, then dependent claims 25-28 and 37 should also become allowable.

## The Rejection of 34 Under 35 U.S.C. § 103 (a)

Claim 34 is rejected under 35 U.S.C. § 103 (a) as being unpatentable over Hayashi et al. (Cancer Research, July 1994, Vol. 54, p 3853-3856), in view of Gonzalez-Zulueta (Cancer Research 1993), Merlo et al. (Cancer Research 1994), and Ah-See et al. (Cancer Research, 1994). Claim 34 has been canceled, rendering this rejection moot.

# The Rejection for Obviousness-Type Double Patenting

Claims 24-28, 37 and 42 are rejected under the judicially created doctrine of obviousness-type double patenting. The claims are said to be obvious over U.S. Patent No. 6,235,470. The claims of the '470 patent are cited as being drawn to detection of head and neck or lung cancer in a saliva sample from a patient.

Claim 42 has been canceled. Claim 24 has been amended to delete saliva, rendering this claim free of the rationale of the rejection. Claims 25-28 and 37 depend from claim 24 and thus should also now be free of the cited patent. The rejection should be overcome.

Respectfully submitted,



Attorney Dkt. No. 001107.76459

Page 5

Date: July 3, 2002

By:

Sarah A. Kagan

Registration No. 32,141

Banner & Witcoff, Ltd. 1001 G Street, NW Washington, DC 20001 202-508-9100

X

Attorney Dkt. No. 001107.76459

Page 6

### **APPENDIX**

23. (Thrice Amended) A method for detecting lung cancer in a sputum specimen, comprising the step of:

testing a plurality of microsatellite markers in the specimen to determine a microsatellite marker length alteration relative to a control sample, wherein a microsatellite marker length alteration in the specimen relative to the control sample indicates the presence of a cancer in a [the] lung which drains into the sputum.

24. (Thrice Amended) A method for detecting cancer of an organ in a specimen of a body fluid which drains the organ, wherein the specimen is selected from the group consisting of: [blood,] urine, sputum, bile, stool, cervical smears, [saliva,] tears, cerebral spinal fluid, and lymph nodes comprising the step of:

testing a plurality of microsatellite markers in the specimen to determine a microsatellite marker length alteration relative to a control sample wherein a microsatellite marker length alteration in the specimen relative to the control sample indicates the presence of a cancer in the organ which drains into the body fluid.

